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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/338,221	06/22/1999	ELI PINES	22553/17	1129

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EXAMINER

GUPTA, ANISH

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 12/31/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/338,221

Applicant(s)

PINES ET AL.

Examiner

Anish Gupta

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 25 is/are pending in the application.
- 4a) Of the above claim(s) 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10-09-02 has been entered.

2. The amendment filed 1-29-02 is acknowledged. Claims 1, 2 and 13 were amended and claims 18-25 and 27-34 were canceled. Claims 1-14 and 26 are pending in this application.

### **Election/Restriction**

3. Applicant's election without traverse of Group I, claims 1-14, in Paper No. 9 is acknowledged. Claim 25 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected Group II and Group III.

4. This application contains claim 25 drawn to an invention nonelected with traverse in Paper No. 9. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### **Claim Rejections - 35 USC § 103**

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was

commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-11 and 13 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Schwarz et al. in view of Tripodi. for the reasons set forth in the previous office action and the reasons set forth below.

6. Claims 1-3, 7-11, and 13-14 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Stroetmann et al. ('650) or Stroetmann et al. ('655) in view of Tripodi et al. for the reasons set forth in the previous office action and the reasons set forth below.

7. Claims 1-3, 5, 7-11, and 13-14 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Stroetmann et al. ('650) or Stroetmann et al. ('655) in view of Tripodi et al. in further view of Farrell et al. for the reasons set forth in the previous office action and the reasons set forth below.

8. Claims 2 and 12 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Stroetmann et al. ('655) in view of Richter (abstract) and Tripode et al. for the reasons set forth in the previous office action and the reasons set forth below.

For all of the rejection, Applicants argue similar points which have been addressed below. All of the rejections are maintained for the reasons outlined in the previous office actions and the reasons set forth below.

The claims are drawn to a therapeutic composition comprising fibrinogen.

Applicants argue that the reference of Schwarz et al. teach in an amount at least 70mg/ml. The instant application, however, provides that the therapeutically effective strength at fibrinogen concentration is only about 10mg/ml. Applicants state that the word "capable" has been removed from the claims.


Applicant's arguments filed 10-09-02 have been fully considered but they are not persuasive.

Schwarz et al. teach a tissue adhesive composition for wound closures that comprise fibrinogen that is capable of cross-linking with fibrin- $\gamma$ -chains after 3 to 5 minutes of incubation (see claim 1) and the secondary reference provides motivation to use bovine fibrinogen. Applicants have argued with respect to concentration. The claims still infer that the concentration can be at 10mg/ml or less but does not have to be used at this concentration. The claim state the solution polymerizes when provided in a solution at said site at the concentration of about 10 mg/ml. This claim language does not require that the concentration be at 10 mg/ml. Further, the recited limitation can be seen as a functional limitation since the limitation can be interpreted as a characteristic rather than a requirement. The reference discloses a fibrinogen composition that is useful in wound closure that is effective on contact with thrombin. The reference meets all of the structural limitation of the claimed composition. Since the reference teaches a composition with all of the structural limitations, such a composition would necessarily possess the functional limitations.

Rejections are maintained.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (703) 308-4001. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can normally be reached on (703)306-3220. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



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